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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,886	04/30/2002	Riccardo Losa	BJS-4662-392	6033

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EXAMINER	
JAGOE, DONNA A	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
08/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/030,886	LOSA, RICCARDO	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,16,18 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,16,18 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments filed March 22, 2007 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 15, 16, 18 and 28 are pending in this application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 15, 16, 18 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nitsas U.S. Patent No. 6,106,838 and Ropapharm WO 96/37210. Nitsas teaches a composition comprising carvacrol and thymol wherein the ratio weight of carvacrol to the weight of thymol is about 50:1 to about 5:1 (see column 17, claims 12). Applicant's weight ration of carvacrol to thymol is from 2:3 to 4:1 falls within the Nitsas' weight ration range. Regarding composition claims 15 and 16, drawn to a medicament for treatment of a disease caused by a strain of *Treponema,* it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably

distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Ropapharm teaches antimicrobial compositions comprising carvacrol and thymol (see entire document) that were effective to treat diseases caused by pathogenic microorganisms of the abdominal tract, such as swine dysentery (page 5, line 46) and further causes of diarrhea, such as those caused by *Treponema hyodesynterie* (see table A, page 5, line 6 and page 6, line 29). Ropapharm differs in that it does not teach the exact weight ratio of 2:3 to 4:1, however, if one looks at the examples throughout, the weight ratios are encompassed therein. One skilled in the art would have been motivated to prepare additional useful compositions of the ranges taught by the prior art. While the reference is silent regarding some % ratios, the difference in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 45, 105 USPQ 233, 235 (CCPA 1955). In the absence of any criticality and/or unexpected results of the additional ranges claimed, the instant invention is considered obvious.

Regarding Applicants assertion that the priority date is a Foreign application to Sweden filed 5/12/1999, Applicant cannot rely upon the foreign priority papers to

overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Response to Arguments

In response to applicant's argument that Nitsas does not teach the surprisingly good effect the claimed invention has towards Treponema and diseases caused by the presence of Treponema, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. See *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.dd 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1554 and MPEP §2112.02(II).

Applicant asserts that WO 96/37210 (Ropapharm) teaches antimicrobial compositions comprising an extraction of essential oils that were effective to treat diseases caused by pathogenic microorganisms of the abdominal tract and further causes of diarrhea. In response, Ropapharm teaches antimicrobial compositions comprising **carvacrol** and **thymol** (see entire document) that were effective to treat

diseases caused by pathogenic microorganisms of the abdominal tract, such as swine dysentery (page 5, line 46) and further causes of diarrhea, such as those caused by ***Treponema*** *hyodesynterie* (see table A, page 5, line 6 and page 6, line 29). Applicant asserts that there is only one example in the reference in which the combination of thymol and carvacrol is specifically mentioned. In response, a reference is good not only for what it teaches by the direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re Opprecht* 12 USPQ2d 1235, 1236 (Fed. Cir. 1989); *In re Bod*e 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Applicant asserts that the extract of Origanum vulgaris which comprises thymol and carvacrol is never used alone and is used in combinations with other extracts and/or active substances. In response, the claim language *comprising* (see instant claims 15, 16, 18 and 28) leaves the claim open for the inclusion of unspecified ingredients, even in major amounts and as such, does not exclude other extracts and/or active substances.

Applicant asserts that Ropapharm discloses many different extracts without further specification of active compounds and many microbial infections which could be treated with the extracts. In response, In response, Ropapharm teaches antimicrobial compositions comprising **carvacrol** and **thymol** (see entire document) that were effective to treat diseases caused by pathogenic microorganisms of the abdominal tract, such as swine dysentery (page 5, line 46) and further causes of diarrhea, such as those caused by ***Treponema*** *hyodesynterie* (see table A, page 5, line 6 and page 6, line 29).

Applicant asserts that because of a lack of sufficient disclosure, the cited prior art documents fail to suggest the use of a specific combination of thymol and carvacrol for treatment of diseased caused by Treponema and/or for treating swine diseases. This is not persuasive because the strongest rationale for combining references is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. See In re Sernaker 17 USPQ 1, 5-6 (Fed. Cir. 1983) and MPEP 2144. Nitsas teaches an antimicrobial composition comprising carvacrol and thymol wherein the ratio weight of carvacrol to the weight of thymol is about 50:1 to about 5:1 (see column 17, claims 12) which overlaps and encompasses the instantly claimed ratio. Ropapharm teaches antimicrobial compositions comprising **carvacrol** and **thymol** (see entire document) that were effective to treat diseases caused by pathogenic microorganisms of the abdominal tract, such as swine dysentery (page 5, line 46) and further causes of diarrhea, such as those caused by ***Treponema*** *hyodesynterie.* It is therefore reasonable to conclude that the strength of correlation between references gives rise to reasonable expectation of success from combining them.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe
Patent Examiner
Art Unit 1614

August 8, 2007

8/12/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER